Application No. 09/560,597
Filed: April 28, 2000
Group Art Unit: 3626

REMARKS

This Amendment is responsive to the Office Action dated August 19, 2002 in the above captioned application for United States Patent. All rejections and objections of the Examiner are respectfully traversed. Reconsideration is respectfully requested.

At paragraphs 2 and 3 of the Office Action, the Examiner rejected claims 1-25 and 28-38 as being obvious under 35 U.S.C. 103(a), citing United States patent number 5,991,731 of Colon et al. ("Colon et al."), in view of "Three Topics Integral to the use of the Internet for Clinical Trials: Connectivity, Communication, and Security" of Hopp ("Hopp"). Applicants respectfully traverse this rejection.

Colon et al. disclose a system for managing data used in conducting clinical studies concerning subjects at a plurality of participating, geographically distributed clinical sites. The Colon et al. system is designed for access by clinicians, or their employees, through computer systems located at the clinical sites. The computer systems of Colon et al. at the clinical sites communicate with an Internet network server computer, which in turn is interfaced to a database host computer.

In the Colon et al. system, a management center operates to manage data used in conducting clinical studies concerning

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subjects associated with geographically distributed clinical sites via the Internet. Colon et al. describe a management center in which an Internet network server computer communicates data over the Internet to determine patient eligibility, randomization and initial prescriptions. A final prescription is printed out for signature and sent electronically in the system of Colon et al. to a distribution center, and study data is maintained in a database behind a firewall provided in the Internet server computer.

FIG. 5 of Colon et al. shows an initial patient visit to the clinical site. A form comes up on the clinical site computer, and patient data is entered relating to identification, demographics and medical conditions. This information is transmitted to the study management center of the Colon et al. system. Data element values are validated by the Colon et al. system at entry, and printouts of the same data are included for the patient's permanent record. With regard to security measures, the disclosure of Colon et al. states that secure transactions are used to pass clinical data over the Internet and conduct clinical study management over the Internet, and that security is achieved by restricting access to all Internet material to authorized users only and encrypting data transmissions. See column 6, lines 34-39.

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Data is sent from the clinical sites to the management center in Colon et al., where an application program in the Internet network server computer executes a test to see if the patient meets the eligibility parameters for the study. If not, then a message of ineligibility is returned to the clinical site by the Colon et al. management center. Otherwise, the Colon et al. system routine assigns the patient to a study, and determines and sends an initial suggested drug prescription to the remote clinical site computer. The Colon et al. system allows an attending physician at the clinical site to then confirm or adjust the prescription by entering data to modify data in a drug prescription form.

Colon et al. further disclose that an administrative office associated with the central computing facility has to authorize access to the system. The database of Colon et al. stores contact information for all study participants and their authorized levels of access. Requests for interaction with the Colon et al. system coming from Internet sites are checked against the management database to assure that only authorized users can access study materials and then only materials appropriate to their role in the study. The Colon et al. disclosure lists the types of system users that are authorized to access the study materials as regional directors, study investigators, and sponsor

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representatives. In this regard, Colon et al. states beginning at line 55 of column 7 that regional directors, investigators and sponsor representatives for the clinical study are issued passwords for the purpose of conducting study-related activities over the Internet. These passwords in Colon et al. are tied to authorized actions and subsets of the data. Specifically, Colon et al. states that 1) site investigator would have the codes to enter eligibility data, randomize subjects, enter follow-up data and review case listings; 2) regional directors would have access to screens for requesting and obtaining on-line management reports for their respective regions, and 3) study investigators and sponsor representatives would have access to study-wide management reports. See column 7, lines 55 through 65.

The Examiner notes in the Office Action that Colon et al. fails to teach or suggest providing instructions on how to use a test substance to a clinical trial participant located at a remote internet site. Accordingly, the Examiner relies on Hopp for its teachings regarding use of the Internet for clinical trials and sharing documents with participants over the Internet.

Enclosed herewith is a Declaration under 37 C.F.R. 1.131, establishing a date of invention at least as early as August 31, 1998. As the date of Hopp is October-December 1998, Applicants respectfully submit that Hopp should not be considered prior art

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with regard to the present application. Since the teachings of Hopp regarding using the Internet for clinical trials and sharing documents with participants over the Internet are not disclosed or suggested in Colon et al., Applicants respectfully urge that no *prima facie* case of obviousness under 35 U.S.C. 103 is present with regard to independent claims 1, 8 and 29 when Hopp is not considered prior art. With regard to dependent claims 2-7, 9-25, 28 and 30-38, they each depend from one of independent claims 1, 8 or 29, and are respectfully believed to be patentable for at least the same reasons.

Moreover, Applicants respectfully urge that even were Hopp considered to be prior art, the combination of Colon et al. and Hopp does not disclose or suggest the invention as set forth in the present independent claims 1, 8 and 29. Hopp discusses connectivity, communication, and security in the area of Internet based clinical trials. In the area of connectivity, Hopp sets forth various points regarding the availability and reliability of the connectivity in certain countries. With regard to communication, Hopp describes a number of data formats and protocols that have applicability in this area, including Adobe PDF, Java, ActiveX, and others. In his discussion of the security issues, Hopp focuses on security over the Internet with regard to intercepted communications on the Internet, with regard to secure

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virtual private networks (SVPNs) that operate utilizing cryptographic techniques. Hopp also discusses the combination of SVPNs with intrusion detection, and postulates that simple to use SVPNs could be sufficient for the needs of clinical trials.

Nowhere in the combination of Colon et al. and Hopp is there disclosed or suggested any system or method of conducting a clinical trial of a test substance over the internet from a primary site, which includes ***assigning a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site, the unique identifier and the unique log-in password for accessing protected information from the primary site,*** where both the ***providing to the participant of instructions on using the test substance, accessing and completing at least one evaluation form from a website maintained at the primary site, and returning electronically said at least one evaluation form to the primary site, and the providing of at least one evaluation form in electronic format for use by the participant, are responsive to receipt by the primary site of the unique identifier and said unique log-in password,*** as in the present independent claims 1, 8 and 29.

In contrast, Colon et al. describe a system in which security measures are only considered for site investigators, regional directors, and study investigators. This reflects the objective

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of Colon et al. to provide a system for use at clinical sites by clinicians and other clinic employees. Accordingly, Colon et al. only describe using passwords with regard to protecting test results and other information entered into the system regarding the participants. There is no disclosure in Colon et al. of even the desirability of password protection provided on a per participant basis, in order to potentially control access to information in the instructions and/or evaluation forms, as in the present independent claims 1, 8 and 29. With regard to Hopp, even if it were to be considered prior art, in the area of security, Hopp only addresses the danger of interception of data between the remote and the central management sites. Hopp, therefore, only describes use of a virtual private network, based on encryption, as a solution to such security problems.

For the reasons stated above, Applicants respectfully urge that:

1) Hopp should not be considered prior art based on the enclosed Declaration under 37 C.F.R. 1.131, establishing a date of invention prior to Hopp, and alternatively that even if Hopp is considered prior that

2) The combination of Colon et al. and Hopp does not disclose or suggest all the elements of the present independent claims 1, 8 and 29. Accordingly, Applicants respectfully submit that the

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combination of Colon et al. and Hopp fails to provide a *prima facie* case of obviousness under 35 U.S.C. 103. As to claims 2-7, 9-25, 28 and 30-38, they each depend from one of claims 1, 8 and 29, and are respectfully believed to be patentable over the combination of Colon et al. and Hopp for at least the same reasons.

At paragraph 4 of the Office Action, the Examiner rejected claims 26 and 27 as being obvious under 35 U.S.C. 103, again citing Colon et al. and Hopp, as well as "Lily warns Nutri System about using Prozac", by Dinah Brin ("Brin"). Applicants respectfully traverse this rejection.

Brin is an article reporting that while there has been some marketing of a drug combination including Prozac by a company specializing in weight loss products, the use of Prozac in such a combination is not endorsed by the maker of Prozac, and may have adverse side effects. The disclosures of Colon et al. and Hopp are discussed above with respect to the rejections in paragraphs 2 and 3 of the Office Action.

Applicants again respectfully submit that Hopp should not be considered prior art, based on the enclosed Declaration under 37 C.F.R. 1.131, establishing a date of invention prior to Hopp. Moreover, Applicants urge that even were Hopp to be considered prior art, nowhere in the combination of Colon et al., Hopp and

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Brin is there disclosed or suggested any system or method of conducting a clinical trial of a test substance over the internet from a primary site, which includes ***assigning a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site, the unique identifier and the unique log-in password for accessing protected information from the primary site***, where both the ***providing to the participant of instructions on using the test substance, accessing and completing at least one evaluation form from a website maintained at the primary site, and returning electronically said at least one evaluation form to the primary site, and the providing of at least one evaluation form in electronic format for use by the participant, are responsive to receipt by the primary site of the unique identifier and said unique log-in password***, as in the present independent claims 1 and 8, from which claims 26 and 27 depend. Accordingly, Applicants respectfully urge that the combination of Colon et al., Hopp and Brin does not disclose or suggest all the elements of the present independent claims 1 and 8, from which claims 26 and 27 depend. The combination of Colon et al., Hopp and Brin therefore fails to provide a *prima facie* case of obviousness under 35 U.S.C. 103 for claims 1 and 8. Claims 26 and 27 which depend from claims 1 and 8, are respectfully believed to be patentable over the combination of

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Colon et al., Hopp and Brin for at least the same reasons. Reconsideration of all pending claims is respectfully requested.

As all claims are believed to be allowable, the application is believed to be in condition for allowance. Favorable action is respectfully requested.

The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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MARKED-UP VERSION OF CLAIM AMENDMENTS

Please cancel claims 15 and 19 without prejudice or dedication.

1. (Amended) A method of conducting a clinical trial of a test substance over the internet from a primary site, comprising the following steps:

assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site distinct from the primary site, the unique identifier and the unique log-in password for accessing protected information from the primary site;

providing to the [at least one clinical trial] participant [located at a remote internet site distinct from the primary site], responsive to receipt by the primary site of the unique identifier and the unique log-in password, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a question and answer section that, when completed by a participant using the test substance, provides information from which a determination can be made of one or more effects

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of the test substance on the participant completing the evaluation form; and

compiling data regarding at least one said effect of the test substance on the participant from information from a received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

8. (Amended) A method of conducting a clinical trial of a test substance over the internet, comprising the following steps:

- maintaining, at a primary site, a website that is accessible from remote sites via the internet and that provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial;
- causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site from the remote site, of a request to display the questionnaire, wherein the questionnaire has portions for receiving information that enables a determination of whether a candidate, upon whose behalf the questionnaire is completed, is eligible to be a participant in the clinical trial;
- obtaining the candidate's informed consent to participate in the clinical trial;
- receiving the candidate's completed questionnaire at the primary site via the internet;
- reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria;

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- after receipt of the candidate's informed consent by at least one investigator, causing information transfer between the primary site and the remote site for the purpose of confirming the existence, identity, and eligibility of the candidate to participate;

- assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant, the unique identifier and the unique log-in password for accessing protected information from the primary site;

- providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, to [at least one clinical trial] the participant [located at a remote internet site distinct from the primary site], instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

- providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a question and answer section from which a determination can be made of one or more effects of the test substance on the participant completing the evaluation form; and

- compiling data regarding at least one said effect of the test substance on the participant from information from a received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

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13. (Amended) The method of claim 1, 2, 7, or 8, further comprising collecting and storing at a secure site accessible by the at least one investigator and by the participant [upon providing a log-in password], information from at least one member of the group consisting of: at least one evaluation form completed and returned by the participant to the at least one investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator.

29. (Amended) A system for conducting a clinical trial of a test substance over the internet from a primary site, comprising at least one computer at the primary site that comprises:

program code for assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site distinct from the primary site, the unique identifier and the unique log-in password for accessing protected information from the primary site;

program code for providing, via the internet, responsive to receipt by the primary site of the unique identifier and the unique log-in password, to at least one clinical trial participant located at a remote site distinct from the primary site, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

program code for providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant at the remote site, said at least one

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evaluation form having a question and answer section that, when completed by a participant using the test substance, provides information from which a determination can be made of one or more effects of the test substance on the participant completing the evaluation form; and

program code for compiling into a central database at the primary site, data regarding at least one said effect of the test substance on the participant from information from a received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

38. (Amended) The system of any of claims 29-36, further comprising means for collecting and storing at a secure site accessible by the at least one investigator and by the participant [upon providing a log-in password], information from at least one member of the group consisting of: at least one evaluation form completed and returned by the participant to the at least one investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator.

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